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This ongoing study used urine LCR to determine the prevalence of and risk factors for chlamydial infections among military females. Three different populations were screened: recruits who were beginning military service, symptomatic patients attending a Troop Medical Clinic (TMC), and asymptomatic women having a PAP test. Urine specimens and questionnaires were collected. Urines were tested by LCR (Abbott Labs); PAP patients were also tested by cervical culture. In 10,361 women screened from 1-96 to 6-97, prevalence was 9.1%. The recruits, TMC, and PAP populations had prevalences of 9.0%, 11.9%, and 7.3%, respectively. The mean age was 22; 50.5% were Caucasian; 94% were sexually active, 25.3% had more than 1 sex partner in the last 90 days; and 29.2% had a new sex partner; 16.2% used condoms consistently; and 9.4% had a previous chlamydial infection. Compared to cervical culture, LCR sensitivity was 88.6% (asymptomatic group, N=434). Multivariate analysis of the recruit population (N= 9,192) identified several significant risk factors useful for predicting chlamydial positivity: young age (OR 3.4), African-American race (OR 2.7), vaginal sex (OR 4.1), more than 1 sex partner (OR 1.4), and a new partner (OR 1.5). For the recruit population, a screening program based solely on young age ( $\geq$ 25) could detect 95.8% of the positives while only screening 87.2% of the population. Preliminary analysis indicates mass therapy is potentially cost-effective in preventing the disease.

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### **FOREWORD**

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### INTRODUCTION

Chlamydia trachomatis infections in the U.S. exceed 4 million cases, annually. Since chlamydial infection may initially be asymptomatic in 70% of women, they frequently remain undiagnosed, resulting in acute and chronic sequelae, such as cervicitis, endometritis, pelvic inflammatory disease, ectopic pregnancy, and infertility. In the U.S., the annual costs of chlamydia infections and their sequelae are estimated at \$5 billion. Infection rates for young, sexually active women range from 5-20%, with rates highest for those under 21, suggesting a high prevalence in incoming female recruits. For example, military PID rates are approximately 5 times higher than the national level. However, a comprehensive prevalence study among military women has never been performed.

Since urine samples have now been demonstrated to be excellent specimens for the detection of *C. trachomatis* when tested by the new molecular DNA amplification test, Ligase Chain Reaction (LCR), it is now possible to rapidly, easily, and accurately screen large numbers of patients for chlamydial infection. Our laboratory had extensive experience in the clinical trials evaluating the LCR test and currently performs the assay routinely for up to 800 samples per week.

This grant will implement and evaluate a chlamydia screening program of active-duty female soldiers. Based upon findings of the study, recommendations will be made for an effective, cost-efficient chlamydia control program designed to reduce morbidity due to *C*. *trachomatis*.

The objectives of this study are to

- 1. Determine the prevalence of infection in several military female populations;
- 2. Determine risk factors predictive of infection;
- 3. Conduct a cost-effectiveness analysis comparing universal screening versus selective screening utilizing risk factor criteria;
- 4. Recommend a chlamydial control program: selective screening and treatment;) universal screening and treatment; or,) mass therapy for all female basic recruits.
  Utilizing ICD codes, we will monitor PID and ectopic pregnancy rates, over the 3 year period of chlamydia screening.

### **BODY**

### **METHODS**

### POPULATIONS AND SPECIMENS.

Three female military populations were studied: Recruits undergoing in processing at the Reception Battalion, Ft. Jackson; Symptomatic active-duty women at the Troop Medical Clinic at Ft. Jackson; and females having a PAP test performed at Ft. Bragg. All participants were voluntarily recruited into the study by a civilian study nurse and have signed a consent form approved by the respective institutional review boards.

Each subject completed a questionnaire for demographic information and sexual risk factor history and provided a urine sample. The questionnaire was a one page, two-sided scannable bubble-form (Scantron Corporation, Tustin, CA). In addition, a endocervical swab for chlamydia culture was obtained by the attending clinician from the volunteers from Ft. Bragg's PAP clinic. Cultures were placed into chlamydia transport medium (2SP). All specimens, consent forms, and questionnaires were shipped to Johns Hopkins University Chlamydia Laboratory, under appropriate environmental conditions (-20° C for urine specimens and on dry ice for the culture specimens).

To determine comparability of the volunteer and non-volunteer recruits at the Reception Battalion, with regard to demographics and risk history, a sub-sample of those non-volunteering recruits were invited to anonymously fill out a questionnaire. This sub-sample was collected on the first Sunday of each month.

### CHLAMYDIA TESTS.

Urines were processed and tested by ligase chain reaction (LCR) [Abbott Labs, Abbott Park, IL] for chlamydial DNA, according to manufacture's directions. The LCR test is now

approved by the FDA for use with both urine and endocervical specimens. The chlamydia cultures were performed in 96-well microtiter plates using McCoy cells, according to standard laboratory procedure.

Discrepant analysis was performed on any discordant sample results from the PAP population at Ft. Bragg. (Discordant defined as either: 1) culture positive/LCR negative; or, 2) culture negative/LCR positive. For the former, LCR was repeated from the stored, frozen aliquot of processed urine, and if still LCR negative, the processed LCR specimen was diluted 1:10 and retested by LCR. In addition, polymerase chain reaction (PCR, Roche Molecular Systems) was performed on a stored frozen aliquot of urine. For the latter, the culture fluid sediment was stained by Direct Fluorescent Antibody (Syva, San Jose, CA) in order to visualize any elementary bodies, characteristic of chlamydia. If positive, this confirmed that the LCR was a true positive test. If the DFA was negative, further testing of the culture fluid by PCR was performed. If the PCR was negative, the LCR was considered to be a false positive test. If the PCR was positive, the LCR result was considered to be a true positive test). The results of these tests were used to determine the sensitivity and specificity of the LCR urine assay as used for this population (PAP).

The scan forms were scanned into a data set (d-base III) and the LCR results, demographics, and risk factor information were analyzed using chi-squared test, Fisher's tests of exactness and logistic regression analysis (Stata, College Station, TX). Data for the multivariate models were recoded as dichotomous variables (presence of risk vs. no risk) according to the findings of the univariate analyses. A cost-effectiveness analysis was conducted using a cost and outcome based decision tree designed in Smltree (Jim Hollenberg, NY 2.9). All consent forms, as well as the original Scantron forms, were stored in a locked file cabinet.

### **RESULTS**

The following anlyses were conducted on cummulative data from January 21, 1996 through June 22, 1997 (see Appendix A for annual break down of data). The exception being the cost-effectivness analysis which was conducted in March, 1997 for report at the Third Annual Uniformed Services Recruit and Trainee Health Care Symposium: 19-21 May 1997, Walter Reed Army Institute of Research; Washington, D.C. (Appendix B) RECRUITS, FT JACKSON: Of 11,777 recruits presenting at the Physical Exam Station, 9,209 (78.2%) volunteered from January 21 to June 23, 1996. This is a 12 percentage point increase over last year's performance. Seventeen individuals either had unevaluable urine specimen or they were missing more than two data items. Evaluable data from 9,192 recruits showed: 87.2% (8012/9192) were age 25 or younger, 51.9% (4771/9192) were Caucasian, 35.1% (3225/9192) were African American, and 13% (1196/9192) were other races. The prevalence for *C. trachomatis* by urine LCR for the population was 9.0% (828 of 9,192).

By questionnaire, 93.6% (8602/9192) reported having had vaginal sex, 26% (2390/9192) had more than 1 sex partner in the previous 90 days, 30.5% (2806/9192) had a new sex partner in the previous 90 days, and only 15.5% (1429/9192) always used condoms. A prior history of chlamydial infections was reported in 8.8% (806/9192), gonorrhea in 3.2% (291/9192), syphilis in 0.6% (52/9192), and trichomonas infection in 4.5% (415/9192).

By age, prevalences for chlamydia were: 10.95% (age 17-20); 8.01% (age 21-25); 3.14% (age 26-30); and 1.85% (age 31-35). For further analyses, the 2 youngest age categories were combined into a variable called "young" (age 17-25; prevalence 9.9% 793/8012). By race, prevalences were 5.3% for Caucasian, 14.4% for African American, and 9.1% for others.

Univariate analysis identified 5 significant risk factors: young age (17-25 years), African

American, ever having vaginal sex, > 1 sex partner, and new sex partner. Condom use and prior diagnosis of chlamydia, gonorrhea, syphilis, or trichomonas were not significant. In the multivariate model, the variables useful as predictors for chlamydial infection were vaginal sex (OR 4.08, 95% C.I. 2.28-7.29), young age (OR 3.41, 95% C.I. 2.41-4.82), African American (OR 2.71, 95% C.I. 2.34-3.14), more than 1 sex partner (OR 1.41, 95% C.I. 1.17-1.70) and having a new sex partner (OR 1.49, 95% C.I. 1.23-1.79). This population is predominant by young sexually active women. Thus, the population is high risk by definition according to other published studies. If young age alone was used as the screening criteria 87.2% of the population would be tested, including 95.8% of the positives. If sexual activity defined as sexual intercourse was used as the screening criteria 93.6% of the population would be tested, including 98.6% of the positive individuals. Combining these two factors would require screening 99.5% of the population, including 100% of the positives. A truly selective sample of the population would be those with reported high risk behaviors such as more than one sex partner or a new sex partner. However, screening on these criteria alone would require testing 20.1% of the population including only 31.5% of the positives. The cost-effectiveness of these screening strategies will be addressed in the final cost-effectiveness analysis.

Non-volunteer Recruits, Ft. Jackson: There were 610 women who filled out a questionnaire, anonymously: very few women had data evaluable for age determination. 33.4% were African American, not significantly different from the volunteers; 3.0% had prior chlamydia, 69.5% had vaginal sex, 17.9% had a new sex partner, and 55.7% did not consistently use condoms(all five characteristics significantly different from those of the volunteers even when vaginal sex was controlled for). 17.9% of the non-volunteers had more than one sex partner in the prior 90 days. This did not differ significantly from the volunteers when vaginal sex was controlled for, however.

TMC PATIENTS, FT JACKSON: Volunteers included 672 symptomatic soldiers. The volunteer rate of those approached was 80%. Demographics included: 85% (571/672) were 25 years of age or younger, 51.2% (344/672)were African American. 12.5% (84/672) had a prior history of chlamydia, 96% (645/672) reported vaginal sex, 23.7% (159/672) had a new sex partner in the previous 90 days, 23.1% (155/672) had more than one sex partner in the past 90 days, and 71 % (480/672) did not consistently use condoms.

Prevalences of chlamydia for this symptomatic group of patients were: 11.9% (80/672) overall; 12.8% for ≤ 25 yr.; 7.9% for Caucasian; and 15.4% for African American. The prevalence of chlamydia by risk category included: prior chlamydia, 13.1%; vaginal sex, 12.3%; new sex partner, 12%; more than one sex partner in the last 90 days, 13.6%; and inconsistent condom use 11.6%.

PAP PATIENTS, FT BRAGG: The volunteer rate approached was 71%. Among 479 asymptomatic volunteers, and one reporting mild symptoms (N=480), demographics included: 55.2% (265/480) were 25 years or younger, 50.8% (244/480) were African American. 17.9% (86/480) had a history of chlamydia, 4.2% (20/480) Gonorrhea, 1.0%(5/480) syphilis, and 8.5% (41/480) trichomonas. 98.3% (472/480) reported vaginal sex, 11.3% (54/480) had a new sex partner in the previous 90 days, 15.2% (73/480) had more than one sex partner in the past 90 days, and 88.5% (425/480) had inconsistent condom use. 30.8% were pregnant.

Fifteen individuals had urine specimen which were missing or unevaluable. Of the remaining 465, the prevalences for chlamydia infection (based on DNA amplification positivity) were: 7.3% (34/465) overall; 11.0% for  $\le 25$  yr.; and 8.9% for African American and 6.5% for pregnant women. The prevalence of chlamydia by risk category included: prior chlamydial

infection, 3.6%; vaginal sex, 7.4%; new sex partner in the prior 90 days, 15.1%; more than one sex partner in the last 90 days, 10.3%; and inconsistent condom use, 7.5%.

In univariate analysis only young age (OR 4.23, 95% C.I. 1.72-10.43) and new sex partner (OR 2.61 95% C.I. 1.11-6.1) were predictors of chlamydial infection. However, when controlling for age new sex partner was no longer significant.

### Ft. Bragg Population Comparison of urine LCR to cervical culture for <u>C.trachomatis</u> (Asymptomatic Population).

There were a total 480 women enrolled from the Ft. Bragg asymptomatic population (PAP Clinics) since the beginning of the study. Of these, there were 46 women, who did not have matching specimen results for comparison. The reasons included: 10 tissue culture toxic cervical culture results and 36 for which there was no cervical culture collected or no urine collected. After removal of these non-matched specimens, there were 434 for comparison purposes. See Tables below.

For the 4 specimens that were positive by culture and negative by urine LCR (4), it was considered by convention that culture was 100% specific and that they were true positives. Thus these were false negatives by LCR.

For the 11 specimens that were culture negative and positive by urine LCR (11), it was considered that they may be true positives or false positives. In order to resolve these discrepant results, another method of analysis was used as a "tie-breaker test". It is well known that chlamydia culture is not 100% sensitive.

The first step in this analysis was to sediment the culture transport vial and to perform a direct fluorescent antibody (DFA) stain for chlamydial elementary bodies (EBs). If Ebs were present it was considered that the culture was falsely negative and the positive LCR result was

confirmed as a true positive.

Additional tests were performed to confirm the positive LCR result as a true positive result. These included repeating the urine LCR, performing PCR for chlamydia (Roche Diagnostic Systems, Bromchburg, NJ) and a research PCR (OMP-1 based) for chlamydia on the archieved urine specimen, and performing LCR for a different DNA target (OMP-1 gene) on the archieved urine specimen. Using these methods of further analysis, all but one positive LCR urine specimen was resolved as a true positive specimen.

### Culture LCR + + 21 11 - 4 398

**LCR** 

+ 31 1 - 4 398

**Infected Status** 

Resolved: Sensitivty 88.6% Specificity 99.7% Positive

Positive Predictive Value 96.9% Negative Predictive Value 99.0%

The Ft. Bragg portion of the project is now complete. A manuscript is in progress.

Cost-effectiveness Analysis: Preliminary Cost-Effectiveness Analysis: We compared universal screening of all recruits to screening only those recruits under 25 years of age and to provision of azithromycin for all recruits at the PES. We estimated that 50% of women developing symptomatic PID within the first 6 months of service would receive an EPTS discharge.

In an estimated annual recruit population of 13, 236 with a chlamydial prevalence of 9.56%, no screening for *Chlamydia trachomatis* would result in a projected illness cost of \$973,000 over a five year period for treatment of 316 cases of silent and symptomatic pelvic inflammatory disease (PID) and related sequelae (chronic pelvic pain, ectopic pregnancies, and infertility).

Screening only those recruits under the age of 25 would require testing 86% of the population and would identify 95% of the chlamydial infections. This screening strategy would cost approximately \$121,000 in screening and treatment expenditures but would save approximately \$580,000 in future sequelae costs including cost of lost training expenditures due to EPTS discharges. This strategy would prevent 227 cases of silent and symptomatic PID.

Testing all recruits would cost an additional \$17,000 but would prevent 12 more cases of PID than screening only young recruits, saving \$37,000 in sequelae costs, including EPTS losses, for an overall savings of approximately \$20,000 over screening only young recruits.

Mass therapy is the most expensive intervention strategy (approximately \$16 per woman), costing \$70,000 more than universal screening. However, this strategy would prevent 32 additional cases of PID saving \$98,000 in sequelae costs for a total savings of \$28,000 over universal testing.

In the recruit population studied, mass therapy appears to be the cost-effective strategy

relative to no screening, screening only young recruits, or testing all recruits. Mass therapy provides for the prevention of chlamydial sequelae and the associated EPTS discharges. Further analysis is underway.

### DISCUSSION IN RELATION TO STATEMENT OF WORK AND PROBLEMS.

For Year Two, the Statement of Work as stated in the grant included 3 tasks.

#5. Proposed: Screening. We will continue to screen approximately 15,000 women by urine

LCR at Ft. Jackson to monitor prevalence. Treatment with azithromycin, 1.0 gram dose orally,

wll be offered to those who are infected with chlamydia.

Performed: Recruitment at Ft. Bragg was completed with a total of 480 asymptomatic women enrolling. Collection continues at the PES at Ft. Jackson. A total of 9209 have volunteered. The total enrollment of symptomatic women at Ft. Jackson's TMC is now 672. Chalmydia positive individuals have been notified and treatment has been documented (1.0 gram dose, orally azithromycin).

Issues: The departure of a second study nurse necessitated down time to hire and retrain a third nurse. Physical relocation of the clinic resulted in lost collection in February, 1997. Recruitment continued to be difficult; i.e., inconsistent show rates for clinic appointments. A decision was made that sufficient test data had been collected in an asymptomatic population to predict the sensitivity and specificity of the urine LCR as compared to cervical culture.

#6.. **Proposed**: Regression analysis. We will determine by regression analysis which risk factors are predictive of chlamydia infection in each of the above population groups.

Performed: The regression analysis for 9,192 female recruits is nearly complete. See Results. It appeared that young age (≤25 yrs.) alone could provide an adequate risk factor upon which to base selective screening; i.e., 87.2% of the population screened would detect 95.8% of positives. #7. Proposed: Cost Analysis. We will determine by cost analysis whether it is more efficient to universally screen and treat, to selectively screen based on risk factors and treat, or to mass treat all female recruits with azithromycin.

**Performed:** <u>Preliminary</u> cost -effectiveness analysis has demonstrated that although mass therapy would appear to be the most expensive intervention strategy, it has the potential to prevent additional cases of PID and other sequalae, providing an overall savings over universal screening in <u>this</u> population.

The decision as to the intervention to be implemented for the 3rd year of collection (January, 1998) is under consideration by our military and civilian collaborators, the Armed Forces Epidemiology Board and the Institutional Review Boards of Johns Hopkins University and Ft. Jackson (Eisenhower, Ft. Gordon).

Issues: The final cost-effectiveness analysis is pending with several issues yet to be resolved by a panel of experts and our military and civilian consultants as to Army specific probabilities and costs to be used in the final model. Such unknowns include:

- 1. Probability of EPTS for discharge due to symptomatic PID;
- 2. Number of outpatient visits associated with PID;
- 3. Probability of PID (Army- specific). We have literature reported probability.
- Probability of Azythromycin associated side effects/cost in military recruits.
   We only have literature reported data.

5. No Army-specific cost of chronic pelvic pain and ectopic pregnancy.

These issues are under consideration our panel as mentioned above in order to decide whether to use data available from civilian sources or to ascertain military specific data, if possible.

### CONCLUSIONS

Urine-based screening for *C. trachomatis* by Ligase Chain Reaction was effective in a female military recruit population, as well as in a symptomatic Troop Medical Clinic population and an asymptomatic PAP clinic population. Acceptance was high, the urine specimens were readily obtained, and the assays were able to be performed quickly and efficiently.

The study has demonstrated a high prevalence (9.0%) for female recruits from a geographically and demographically diverse group, a substantial prevalence (11.9%) from a symptomatic Troop Medical Clinic population, and a higher than expected prevalence (7.3%) from an asymptomatic PAP clinic population. These results have indicated the need for an ongoing chlamydial control program in such female military groups.

Among recruits, risk factor analysis by multivariate logistic regression identified five independent, statistically significant, predictors for being infected with chlamydia: young age, African American, vaginal intercourse, more than one new sex partner, and a new sex partner in the prior 90 days. Women that volunteered from the recruit population appeared to have behavioral characteristics that put them at high risk for chlamydial infections. Women, who were non-volunteers appeared to be similar demographically and many also practiced high risk behavior, but were significantly less likely to have these risk factors (prior chlamydia infection, vaginal sex, new sex partner, more than one sex partner, and inconsistent condom use) than were the volunteers.

Although the women from the symptomatic (TMC) and asymptomatic (PAP) groups had prevalences that were higher than the recruit population, their demographic and risk factor profiles were similar. The numbers of women enrolled at the present time are insufficient to perform univariate or multivariate regression analyses.

A chlamydial screening program that focused on screening all young female recruits (age 25 or less) would require that 87.2% of this population would be screened and 95.8% of all positive infections would be identified. Such a screening program as this, which employed urine LCR testing, has the potential to prevent pelvic inflammatory disease and ectopic pregnancy in Army women.

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### APPENDIX A

Table 1. Characteristics of Military Women Screened for *Chlamydia trachomatis* at Fort Jackson (PES) Recruits: (n = 9,192)

Variables	No.	%
Mean Age, years (range)	22	(17 - 40)
Ethnicity		
White	4,771	51.9
African American	3,225	35.1
Other (American Indian,	1,196	13.0
Alaskan, Asian Pacific)		
Military Category		
Enlisted	9,187	99.9
Officer	5	.05
Having had vaginal sex	8,602	93.6
Sexual History (past 90 days)		
More than one sex partner	2,390	26
New sex partner	2,806	30.5
Consistent condom use	1,429	15.5
Inconsistent condom use	7,289	79.3
Previous Diagnosis		
Neisseria gonorrhoeae	291	3.2
Chlamydia trachomatis	806	8.8
Syphilis	52	.6
Trichomonas	415	4.5
None	7,943	86.4
Chlamydia Positive LCR	828	9.0

Table 2. Characteristics of Volunteers and Non-Volunteers Fort Jackson Recruits

	Volunteers	Non-Volunteers
	(n = 9192)	(n = 610)
Age		
Race, %		
White	51.90	49.18
Black	35.08	33.44
American Indian/Alaskan	1.16	1.15
Asian/Pacific	2.45	2.95
Other <sup>a</sup>	9.40	13.28
Ever having had vaginal sex	93.58	69.51
New sex partner, last 90 days s <sup>†</sup>	30.53	17.87
More than one sex partner, last 90 day	26.0	17.87
Condom use with every sex act, last 90 days	15.55	21.48
Previous STD		
chlamydia <sup>††</sup>	8.77	2.95
gonorrhea <sup>‡‡</sup>	3.17	1.15
syphilis	.57	.66
trichomonas***	4.51	1.97
none ***	86.41	87.38

P = .004 P ≤ .000

<sup>\*</sup>  $P \le .000$ †  $P \le .000$ , P = .001 when control for vaginal sex
† P = .001, P = .164 when control for vaginal sex
\*\*  $P \le .000$ ,  $P \le .000$  when control for vaginal sex
!!  $P \le .000$ ,  $P \le .000$  when control for vaginal sex
!!  $P \le .007$ , P = .049 when control for vaginal sex
\*\*\* P = .004, P = .062 when control for vaginal sex
!!! P = .500, P = .043 when control for vaginal sex

Table 3. Univariate Analysis: Factors Associated with Chlamydial Infection Fort Jackson Recruits:

	% Risk of Infection			
Factor*	Factor Absent	Factor Present	Odds Ratio (95% C.I.)	
Age ≤ 25 (8,012)	2.97	9.90	3.6 (2.55,5.07)	
Black race (3,225)	6.10	14.39	2.6 (2.24, 2.99)	
Having ever had vaginal sex (8,602)	2.03	9.49	5.1 (2.84, 8.72)	
Having had ≥ 1 sex partner, last 90 days (2,390)	7.42	13.51	1.95 (1.68,2.35)	
Having had a new sex partner, last 90 days (2,806)	7.36	12.76	1.8 (1.59, 2.13)	

*Note*. P≤ .000

<sup>\*</sup>numbers in parentheses indicate the number of women for whom the factor was present

Table 4. Factors Associated Independently with Chlamydial Infection Fort Jackson Recruits:

Factor	Beta Coefficient	Odds Ratio (95% C.L.)
Constant	-1.12	•••
Age ≤ 25	-1.23	3.4 (2.41, 4.82)
Black race	998	2.7 (2.34, 3.14)
Having ever had vaginal sex	-1.41	4.1 (2.28, 7.29)
Having had ≥ 1 sex partner, last 90 days	343	1.4 (1.17, 1.70)
Having had a new sex partner, last 90 days	.397	1.5 (1.23, 1.79)

*Note*. P≤ .000

Table 5. Strategies for Selective Testing for Chlamydial Infection Fort Jackson Recruits

Strategy	Risk Factor	Sensitivity %	Specificity %	% Identified as Higher Risk	Positive Predictive Value, %	1-Negative Predictive Value, %	Cases Missed
A	Y,B,V,N,M*	100	.32	99.7	9.03	0	0
В	Y,V	100	.5	99.5	9.05	0	0
C	Y,B,N,M	99.3	6.85	93.68	9.52	1.38	8
D	Y,B,N	99.3	7.35	93.22	9.57	1.28	8
E	Y,B,M	98.9	7.41	93.16	9.56	1.43	9
F	V	98.6	6.91	93.58	9.49	2.03	12
G	Y,B	98.4	9.04	91.63	9.68	1.69	13
H	Y	95.8	13.69	87.16	9.90	2.97	35

<sup>\*</sup>Y= young age, B= Black, V= vaginal sex, N=newsex partner, M=more than 1 sex partner

Table 6. Characteristics of Military Women Screened for *Chlamydia trachomatis* at Fort Jackson (TMC) (n = 672)

Variables	No.	%
Median Age, years (range)	22	(18-46)
Ethnicity <sup>†</sup>		
White	267	39.7
African American	344	51.2
Other (American Indian,	58	8.6
Alaskan, Asian Pacific)		
Military Category		
Enlisted	667	99.3
Officer	4	.6
Reason for Test		
Sex partner of infected	3	.45
individual		
Complaint of symptoms	2	.3
Screening	669	99.6
Other	0	
Clinical Presentation ***		
Mucopus	91	13.5
Cervicitis	56	8.3
Ectopy	14	2.1
Cervical motion tenderness	12	1.8
Friability	12	1.8
Pregnant	25	3.7
Normal exam	23	34.7
Sexual History (past 90 days)		
More than one sex partner	155	23.1
New sex partner	159	23.7
Consistent condom use	192	28.6
Inconsistent condom use	480	71.4
Previous Diagnosis		
Neisseria gonorrhoeae	30	4.5
Chlamydia trachomatis	84	12.5
Syphilis	3	.4:
Trichomonas	84	12.5
None	506	75.3
Chlamydia Positive LCR	80	11.9

4:

<sup>†</sup> Data missing from three women (.45%). ••• Data missing from forty-seven women (7.0%).

Table 7. Characteristics of Military Women Screened for Chlamydia trachomatis at Fort Bragg, SC (n

Variables	No.	%
Median Age, years (range)*	25	(19-47)
Ethnicity <sup>†</sup>		
White	181	37.7
African American	244	50.8
Other (American Indian,	52	10.8
Alaskan, Asian Pacific)		
Military Category*		
Enlisted	439	91.5
Officer	36	7.5
Reason for Test <sup>‡</sup>		
Sex partner of infected	1	.2
individual		
Complaint of symptoms	1	.2
Screening	470	97.8
Other	4	.8
Clinical Presentation***		
Mucopus	1	.2
Cervicitis	5	1.0
Ectopy	5	1.0
Cervical motion tenderness	3	.6
Friability	39	8.1
Pregnant	148	30.8
Normal exam	348	72.5
Sexual History (past 90 days)		
More than one sex partner	73	15.2
New sex partner	54	11.3
Consistent condom use	51	10.6
Inconsistent condom use	425	88.5
Previous Diagnosis <sup>†‡</sup>		
Neisseria gonorrhoeae	20	4.2
Chlamydia trachomatis	86	17.9
Syphilis	5	1.0
Trichomonas	41	8.5
None	348	72.5
Chlamydia Positive LCR	34	7.1
Chlamydia Positive Culture	24	5.0

Data missing from eight women (1.7%).

<sup>&</sup>lt;sup>†</sup> Data missing from three women (.6%).

<sup>&</sup>quot;Data missing from five women (1.0%).

Data missing from five women (1.0%).

<sup>\*\*\*</sup> Data missing from twenty-seven women (5.6%).

<sup>&</sup>lt;sup>††</sup> Data missing from two women (.4%).

Table 8. Univariate Analysis: Factors Associated with Chlamydial Infection Fort Bragg, Patients

	% Risk of	Infection		
Factor <sup>a</sup>	Factor Absent	Factor Present	Odds Ratio (95% C.L.	.)
Age $\leq 25 (254)$	2.8	11.0	4.2 (1.72, 10.43)	
Having had a new sex partner, last 90 days (53)	6.8	15.1	2.6 (1.11, 6.10)	

*Note*. P≤ .05

<sup>\*</sup>numbers in parentheses indicate the number of women for whom the factor was present

<sup>\*</sup>newsex is not significant when controlled for age.

### APPENDIX B

## Chlamydia Screening by Risk Factor in Female n = 9.192Recruits

I							
% Positives Identified	100	100	66	66	98.9	98.4	95.8
% to Screen	99.7	99.5	93.7	93.2	93.2	91.6	87.2
>1 Sex Pt.	×		×		×		
New	×		×	×			
Vag.	×	×					
AfrAmer.	×		×	×	×	×	•
Young	×	×	×	×	×	×	×
Strategy		=		2	>	>	

## n = 9,192Recruit Population Multivariate Analysis

/ariable O.R. 95% C.I.	/ears of age 3.4 (2.41-4.82)	an American 2.7 (2.34-3.14)	ginal Sex 4.1 (2.28-7.29)	Sex Partner 1.5 (1.23-1.78)	1 1 17_1 70)
Variable	< 25 years of a	African Ameri	Vaginal Sex	New Sex Part	1 Cox Dorthor

## Urine LCR Sensitivity and Specificity Compared to Cervical Culture Asymptomatic Population N = 434\* (PAP Clinic)

Infected Status\*\* 398 LCR 398 Culture

Spec 99.7% Resolved Sens 88.6%

NPV 99.0% PPV 96.9%

\*\* Resolved by DFA, PCR (OMP-1, plasmid genes), LCR OMP-1 \*480 women enrolled--46 w/o matching specimens = 434

# State of Origin: New Army Recruit % Ct Positive

(n=9,209)

(# of women coming from each state)



### APPENDIX C

### 3RD ANNUAL

**Uniformed Services** 

### RECRUIT & TRAINEE HEALTH CARE

Symposium

### **AGENDA**

"Reducing Attrition, Promoting Health"

> STERNBERG AUDITORIUM (WRAIR BUILDING)

Walter Reed Army Institute of Research Washington, DC

May 19-21 1997

### **HEALTH PROMOTION SECTION**

1300-1330	Nutrition for Performance/Power Performance Video MAJ Ann Grediagin, MS, USA Directorate of Health Promotion and Wellness USACHPPM, Aberdeen Proving Ground, MD
1330-1350	"Recruit Tobacco Cessation Counseling Project" LT David P. Murphy, MC, USN Recruit Medicine Clinic, Naval Hospital, Great Lakes, IL
1350-1410	"Recruit Dermatology Screening and Education Project" ENS Gregory D. Buttolph, MSC, USN Physician Assistant, Naval Hospital, Great Lakes, IL
1410-1430	Oral Health of U.S. Military Recruits LTC Michael C. Chisick, DC, USA Directorate of Health Promotion and Wellness USACHPPM, Aberdeen Proving Ground, MD
1430-1500	Break (Exhibit Area Outside Sternberg Auditorium)
1500-1520	Evaluating Auditory Readiness in the Recruit Population: Ensuring a Fighting Force for Tomorrow LCDR Anne R. Shields, MS, USN MAJ Kathryn E. Gates, MS, USA Hearing Conservation, Directorate of Clin. Prev. Med. USACHPPM, Aberdeen Proving Ground, MD
1520-1540	Vision Conservation in Recruits LCDR Lee L. Cornforth, MSC, USN Vision Conservation, Directorate of Clin. Prev. Med. USACHPPM, Aberdeen Proving Ground, MD
1540-1600	What is Health Promotion and Why is it Important for Readness? Ms. Judy Harris Directorate of Health Promotion and Wellness USACHPPM, Aberdeen Proving Ground, MD
1600-1620	Health Promotion Panel Discussion (Above Speakers) Moderator: LTC (P) Joan Eitzen, ANC, USA
1620-1700	Poster Session Awards, Concluding Remarks
1700 Division of Pi	Retirement of Colors reventive Medicine Walter Reed Army Institute of Research Washington DC

	PHYSICAL FITNESS AND INJURY SECTION	Wednesd	Wednesday, May 21
1315-1335	Recruit Physical Fitness, Training and Injuries in the	0730-0800	Continental Breakfast (WRAIR)
	80s and 90s COL Bruce Jones, MC, USA		ADHD AND BEHAVIORAL HEALTH SECTION
	Director, Epidemiology and Disease Surveillance USACHPPM, Aberdeen Proving Ground, MD	0800-0850	"Im Going to Kill Myself If You Don't Let Me Out of th
1335-1355	The Fort Leonard Wood Recruit Injury Study MAJ Leo Mahony, MS, USA Directorate of Health Promotion and Wellness		Army MAJ E. Cameron Ritchie, MC, USA Department of Psychiatry Walter Reed Army Medical Center, Washington, DC
1355-1415	USACHPPM, Aberdeen Froving Glound, MD BREAK (exhibit area outside Sternberg Auditorium)	1080-0300	What do You do with recruits who have a history of ADHD?
1415-1425	The Fitness Training Company at Fort Jackson, SC CPT Paul Stoneman, SP, USA		Director, Physical Qualifications and Review Bureau of Medicine & Surgery, Washington, DC
	Company Commander, Figuress Training Co. 1201. Fort Jackson, SC	0300-0350	The Mental Health Emergency Room at
1425-1445	Stress Fractures in Marine Corps Females CAPT Ken Long, MC, USN Senior Medical Officer, Branch Medical Clinic		MAJ (sel) Jeff Cigrag BSC, USAF Chief, Behavioral Analysis Service 59th Medical Wing, Lackland, AFB, TX
	Parris Island, South Carolina	0920-0945	Break (Exhibit Area Outside Sternberg Auditorium)
1445-1505	Stress Fracture Rehabilitation Challenges and Outcomes at the Navy's Recruit Training Command, Illinois LCDR Scott R. Johnson, MSC, USN Nayai Hospital, Great Lakes, Illinois	0945-1005	Psychological Services for the Recruit Convalescent Unit Dr. Carolyn F. Andrews, Clinical Psychologist Recruit Evaluation Unit, Naval Hospital, Great Lakes, IL
1505-1525	The Fort Benning Injury EPICON Study	1005-1025	Sexual Harassment/Sexual Misconduct at Basic Training
	MAJ William C. Hewitson, MC, USA Ms. Michelle L. Canham Directorate of Epidemiology and Disease Control USACHPPM, Aberdeen Proving Ground, MD		COL John A. Fulmer,, AG, USA Deputy Commander of Personnel, U.S. Army Training and Doctrine Command, Fort Monroe, VA
1525-1600	Physical Fitness and Injury Panel Discussion (Above Speakers) Moderator: COL Bruce H. Jones MC, USA	1025-1130	ADHD and Behavioral Health Panel Discussion (Above Speakers) Moderator: CDR Larry K. Grubb, MC, USN

Lunch

1130-1300

Poster Session #2 (3rd Floor WRAIR) (Judging)

1600-1700

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"Sexual Risk Behaviors of Recruits at Fort Jackson, S.C." LTC (P) Joan Eitzen ANC, USA USACHPPM, Aberdeen Proving Ground, MD	"Serum Titer Directed Immunization" LCDR Margaret A.K. Ryan MC, USA	Head, Division of Preventive Medicine Naval Hospital, Great Lakes, Illinois	BREAK (exhibit area outside Sternberg Auditorium)	Booster Prenomenon Associated with Sequential Tuberculin Skin Testing in Marine Recruits CDR Edward Gastaldo MC. USN	Medical Epidemiologist, Beaufort, SC	"Respiratory Disease Control in Military Basic Training	CAPT (sel.) Greg Gray, MC, USN Naval Health Research Center, San Diego, CA	"National Military Invasive <i>Streptococcus pyogenes</i> Surveillance" Mr. Tony Hawksworth, Naval Health Research Center	San Diego, CA	"National Military Advenovirus Surveillance" Dr. Pulak Goswami, Naval Health Research Center San Diego, CA	"Advenovirus: A Past and Present Treat" COL Joel C. Gaydos, MS, USA	Director, Cilnical Preventive Medicine USACHPPM, Aberdeen Proving Ground, MD	Infectious Disease Panel Discussion	Moderator: CAPT Jon D. Bayer MC, USN	Lunch (box lunches/poster session #1/3rd Floor, WRAIR)
0840-0905	0802-0830		0930-0945	0945-1015 ↓		1015-1045		1045-1055		1055-1105	1105-1140		1140-1200		1200-1315
Cost Effectiveness Analysis of PAP Smear Screening at Basic Training CAPT Ken Long MC, USN Senior Medical Officer, Branch Medical Clinic	Parris Island, South Carolina	Exercise Related Mortality in Recruit Basic Training COL John W. Gardner MC, USA Professor of Epidemiology USUHS, Bethesda, Maryland	Buses depart to the Navy Officers' Club for dinner	Dinner at Navy Officers' Club	Special Awards for the Developers of the	Adeliovillas Vaccinas.	Dr. Hobert M. Chanock Dr. Harold S. Ginsberg Dr. Robert Couch	MG (Ret.) Philip K. Russell MC, USA COL (Ret.) Franklin H. Top MC, USA COL (Ret.) Edward L. Buescher Jr., MC, USA	Presentation of Awards by:	Reducing Attrition, Promoting Health: An Historian's View" Special Guest Speaker:		luesday, May 20	Continental Breakfast (WRAIR)	INFECTIOUS DISEASE SECTION	"Chlamydia Screening in Recruits"  Dr. Charlotte Gaydos, Assistant Professor, Infectious Disease Division, School of Medicine,
1615-1630		630-1700	1800	830-2000							E	luesas	0730-0800	*	)800-0840 ,

Registation; Mologne House Walter Reed Army Medical Center	1020-1110	Attrition at a U.S. Army Training Center MG William J. Bolt, USA Commanding General
y, May 19		Fort Jackson, South Carolina
Breakfast and Registration; Sternberg Auditorium Walter Reed Army Institute of Research (WRAIR)		COL Dale Carroll MC, USA Commander USAMEDDAC, Fort Jackson, South Carolina
Posting of the Colors/Service Songs	1110-1200	Attrition at the Coast Guard's Basic Training Base
Welcome from the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM)		Director of Training Cape May, New Jersey
BG Patrick D. Sculley, USA Commander USACHPPM, Aberdeen Proving Ground, Maryland		LCDR Maura Dollymor, PHS Director of Health Services Cane May New Jersey
Overview of Symposium/Administrative Information LTC (P) Patrick W. Kelley MC, USA	1200-1330	Lunch (Local)
Director, Division of Preventive Medicine WRAIR, Washington DC	1330-1400	Attrition/
LTC Ralph Loren Erickson MC, USA Program Manager, Professional Medical Education USACHPPM, Aberdeen Proving Ground, Maryland		I ne Need for Objective Measures  Dr. John F. Mazzuchi  Deputy Secretary of Defense for Clinical Services  Pentagon, Washington, DC
The Personnel Costs of Attrition LTG Normand G. Lezy, USAF Deputy Assistant Secretary of Defense for Military Personnel Policy, Pentagon, Washington DC	1400-1430	Accession Medical Standards/Introduction to the AMSAR LTC (P) Patrick Kelley MC, USA Director, Division of Preventive Medicine, WRAIR, Washington, DC
The Navy's Perspective on Attrition RADM Kevin P. Green, USN Commander, Naval Training Center Great Lakes, Illinois	1430-1500	The Accession Asthma Standard CPT Kathryn L. Clark MC, USA Division of Preventive Medicine, WRAIR, Washington, DC
Break (Exhibit area-Sternberg Auditorium)	1500-1530	Break (Exhibit area-Sternberg Auditorium)
The MEPCOM Perspective on Attrition COL Lawrence J. Fetters MC, USA Command Surgeon USAMEPCOM, N. Chicago, Illinois	1530-1615	Medical Accession Standards Panel Discussion (Members of the DoD Working Group) Moderator: COL Thomas E. Baldwin MC, USAF

0850-0920

0940-1000

- 1000-1020

0920-0940

0815-0830

Monday, May 19

0700-0800

0800-0815

Sunday, May 18

1800-2000

0830-0850

Use of Urine Ligase Chain Reaction (LCR) to diagnose C. trachomatis in female soldiers at Ft. Jackson and Ft. Bragg.

C.A.Gaydos, D.Pham, M.R.Howell, B.Pare, D.Ellis, K.Clark, K.McKee, R.Hendrix, J.Gaydos, T.C. Quinn, Johns Hopkins Univ, Balt. MD. Ft. Jackson, SC, Ft Bragg, NC, CHPPM, Aberdeen, MD, NIH, NIAD, Bethesda, MD.

This ongoing study used urine LCR to determine the prevalence of and risk factors for chlamydial infections among military females. Three different populations were screened: recruits who were beginning military service, symptomatic patients attending a Troop Medical Clinic (TMC), and asymptomatic women having a PAP test. Each soldier provided a urine and answered a questionnaire. Urines were tested by LCR (Abbott Labs) and the PAP patients were also tested by cervical culture. In 5,096 women screened, the prevalence was 8.6%. The recruits, TMC, and PAP populations had prevalences of 8.2%, 12.1%, and 7.1%, respectively. The mean age was 22; 50.5% were Caucasian; 23.9% had more than 1 sex partner in the last 90 days; and 26.3% had a new sex partner. Only 17.1% used condoms consistently; 9.7% had a chlamydial infection previously. Univariate analysis identified several risk factors useful for predicting chlamydial positivity: young age, African-American race, more than 1 sex partner, and a new partner. Urine-based screening was effective in screening large numbers of women and was highly acceptable. Compared to culture, the sensitivity of LCRwas 88.2% in the asymptomatic group. A universal or targeted screening program is being developed and should prevent acute chlamydial morbidity and sequelae such as PID.

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### COST-EFFECTIVENESS OF SCREENING vs MASS THERAPY FOR C. TRACHOMATIS IN FEMALE ARMY RECRUITS

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Objective: In US Army women C. trachomatis (CT) may cause a significant degree of morbidity. We sought to assess the relative cost-effectiveness of three screening and treatment strategies for CT in a military setting.

Methods: We compared universal and targeted screening to mass therapy with azithromycin for CT in female recruits using a cost-effectiveness analysis. At Fort Jackson, SC 7,191 recruits presenting for basic training from 1/96-3/97 were tested by urine LCR for CT. In a decision model from a military perspective, we assessed the total costs (program, medical, and military) and the level of prevented disease due to CT (PID, chronic pelvic pain, and ectopic pregnancy) associated with each of the 3 strategies. Results were extrapolated to an annual cohort of 13,236 recruits.

Results: The recruit sample had a CT prevalence of 9.56% and a diverse ethnic and geographical background. Approximately 86% were ≤ 25yrs old.

Strategy n = 13,236	Projecte (US\$1		Projected PID (#) (silent &symptomatic)
	Program	Sequelae	
No Intervention		\$973,100	316
Screen 425 yrs & Treat (+)	\$120,600	\$273,000	89
Screen All & Treat (+)	\$137,900	\$236,400	<b>7</b> 7
Mass Therapy	\$207,400	\$138,600	45

Mass therapy dominated both screening strategies, costing ~\$16/woman and saving \$627,100 over a projected 5 year period (8.2% and 4.9% more than targeted and universal screening, respectively).

Conclusion: Mass therapy in a well defined cohort of young women with a high prevalence of CT would prevent sequelae, would likely decrease the number of discharges for medical reasons in the first 6 mos. of service, and would save overall costs.

Part 5. The author affirms that the material submitted has not been previously published or presented at any national or international meeting, any experimentation has been conducted according to a protocol approved by the institution, committee on human research or, if no such committee exists, by one which conforms with the principles of the Declaration of Helsinki of the World Medical Association (Clinical Research 14: 193. 1966). The undersigned also certifies that all authors named in the abstract have agreed to its submission for presentation at the International Congress of Sexually Transmitted Diseases, October 19-22 1997.

Author signature

Date

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